Initial Approval: July 10, 2013

CRITERIA FOR PRIOR AUTHORIZATION

Alpha Interferon

PROVIDER GROUP Pharmacy

Professional

MANUAL GUIDELINES The following drug requires prior authorization:

Peginterferon alfa-2a (Pegasys®)

CRITERIA FOR CHRONIC HEPATITIS B Must meet all of the following:

- Patient must have a diagnosis of chronic hepatitis B
- Patient must have been serum HBsAg positive for at least 6 months
- Patient must have evidence of HBV replication defined as one of the following
 - HBeAg positive patients HBV DNA level >20,000 IU/mL
 - o HBeAg negative patients HBV DNA level ≥2,000 IU/mL
- Patient must have evidence of active liver disease demonstrated by one of the following
 - persistent elevation in serum ALT (≥2 times upper limits of normal)
 - o moderate to severe hepatitis or fibrosis on biopsy
 - o evidence of icteric ALT flare ups
- Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Patient must not have decompensated liver disease
- Patient has not previously completed a full course of therapy with interferon or peginterferon

LENGTH OF APPROVAL FOR CHRONIC HEPATITIS B 48 weeks

CRITERIA FOR INITIAL APPROVAL FOR CHRONIC HEPATITIS C (DOES NOT APPLY TO PATIENTS USING TRIPLE THERAPY)

Must meet all of the following:

- Patient must have a diagnosis of chronic hepatitis C
- Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
- Patient must be 5 years of age or older
- Patient has a detectable hepatitis C viral level (HCV RNA) in the serum
- Patient is positive for HCV antibodies
- Patient must not have decompensated liver disease
- Must be taken in combination with ribavirin unless patient has a contraindication or intolerance to ribavirin therapy
- Patient has not been previously treated with interferon alfa

RENEWAL CRITERIA FOR CHRONIC HEPATITIS C Must meet all of the following:

Patient must have an undetectable HCV-RNA at week 24

LENGTH OF APPROVAL FOR CHRONIC HEPATITIS C 24 weeks (up to 48 weeks of total therapy)

WHEN USED WITH TRIPLE THERAPY PATIENT MUST MEET CRITERIA FOR PROTEASE INHIBITOR FOR APPROVAL OF PEGASYS